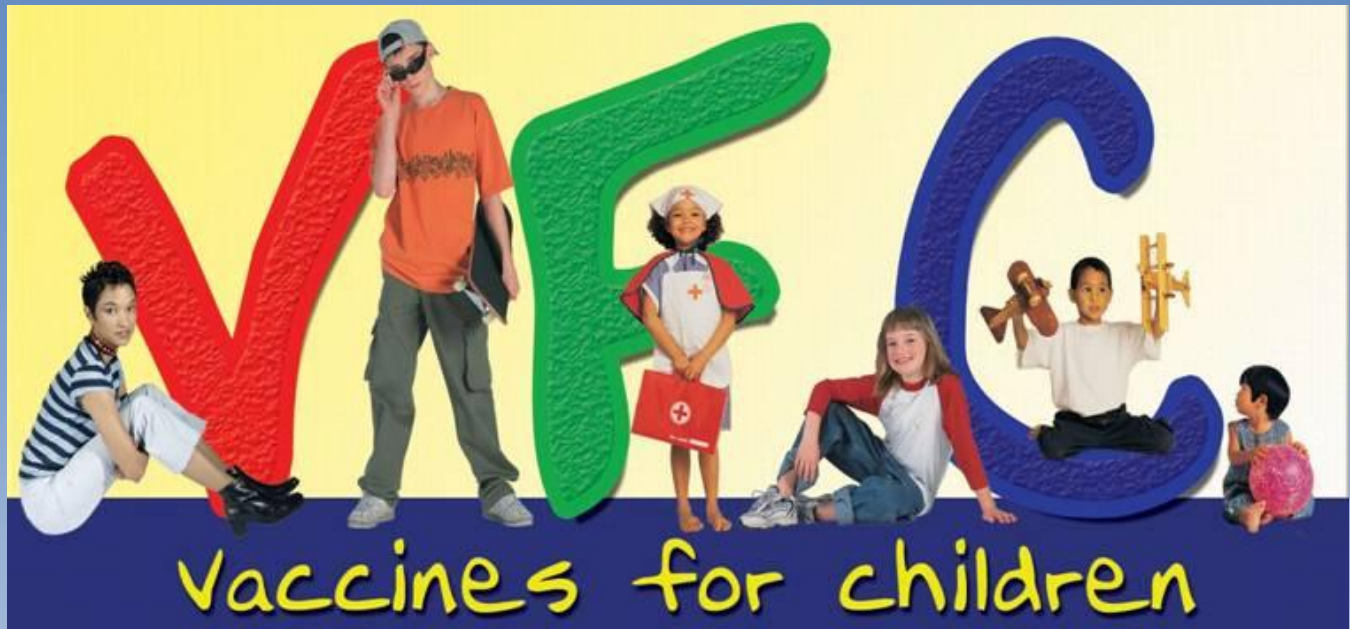


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Montana Department of Public Health and Human Services  
Immunization Program

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# Provider Handbook/ Vaccine Management Plan

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# **VFC Provider Handbook**





## 1. INTRODUCTION

Vaccines for Children (VFC) is a federally funded entitlement program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. It was created through federal law ([42 USC § 1396](#)) and is administered by the Centers for Disease Control and Prevention (CDC) as a component of each state's Medicaid plan. Children through 18 years of age who meet eligibility requirements can receive VFC vaccine. Since its inception in 1994, the VFC Program has improved vaccine availability, increased immunization coverage, and reduced disparities in access to health care.



### ***VFC in Montana***

The Montana Immunization Program implements the VFC Program within the state. We manage the budget, order vaccines, and enroll immunization providers. We educate providers on VFC requirements and ensure compliance through periodic site visits. Our two main goals are to make sure VFC vaccine is at your clinic when you need it and that you are complying with the program's federally mandated requirements.

### ***Funding***

Publicly supplied vaccines in Montana are funded through four main sources: VFC, Section 317 of the US Public Health Service Act (317), State appropriations, and occasionally, Federal grants. As a Medicaid entitlement program, the VFC budget adjusts annually to cover all recommended childhood vaccines for Montana's VFC-eligible children. Vaccine programs funded from other sources, however, may offer different vaccines, serve different populations, and have different requirements than the VFC Program. They vary from year to year in response to State and Federal budgets, public health concerns, and grant objectives.

### ***VFC Document Retention***

VFC providers must retain all VFC-related documents for three years. This includes eligibility screening documents, temperature logs, monthly reports, borrowing forms, and any forms or reports specific to your facility.

### ***This Document***

This document is organized in numbered sections and divided into two main parts: the **VFC Provider Handbook** (Sections 1–10) and the **Vaccine Management Plan** (Sections 11–17). Forms used in the VFC Program change frequently and are not included in this handbook. You can find current forms at [www.immunization.mt.gov](http://www.immunization.mt.gov) under

the VFC link or contact the Immunization Program at 444-5580. A list of forms provided on our website can be found in Section 10 – Immunization Resources.

The Montana Immunization Program provides a paper copy of this document to all enrolled providers and posts the most current version on our website. Sections are revised individually and have a revision date at the bottom of each page. When revisions are made, the Montana Immunization Program will notify you through an all-provider memo, provide a copy of the revised section, and post the revised section to our website. It is your responsibility to keep your copy up to date by discarding outdated sections and replacing them with the most current versions. This document is designed for duplex (2-sided) printing.

## 2. PROVIDER ENROLLMENT

### ***Who can enroll?***

The VFC Program was created to increase access to health care and allow children to remain in their medical homes for immunizations. Any Montana health care provider licensed in good standing with independent prescription writing authority for vaccines can enroll in the VFC Program. This includes both public and private facilities and those not registered as Medicaid providers.



VFC providers must have equipment capable of properly storing vaccines as defined by the State *Vaccine Management Plan* (contained in this handbook starting with Section 11) and must be willing to implement the program requirements. Providers should determine if they serve a sufficient number of eligible patients to justify enrollment in the program (see Section 3 – VFC Eligibility).

Individuals and facilities on the “List of Excluded Individuals and Entities” published by the Department of Health and Human Services, Office of the Inspector General (<http://exclusions.oig.hhs.gov/>) are prohibited from participating in federally funded health care programs including the VFC Program. The Montana Immunization Program must terminate or decline to enroll any provider that is on the list or employs a person on the list.

### ***Re-Enrollment – Current Providers***

Each year, typically in the spring, all VFC providers must re-enroll by submitting an updated Provider Agreement and Provider Profile to the Montana Immunization Program. The Montana Immunization Program will contact you prior to the enrollment deadline with instructions on how to re-enroll for the coming year.

- **Provider Agreement** – This document lists the federal statutory requirements of the VFC Program as defined in [42 USC § 1396](#). It must be signed by the medical director or equivalent at your facility and list all personnel with a medical license authorized to write prescriptions on page 2. By signing this document, your facility agrees to abide by the requirements of the VFC Program.
- **Provider Profile** – This document provides contact information for your facility, including a shipping address for vaccines (no PO boxes), and days and times when vaccines can be received. This information is entered into our vaccine ordering system. On page 2, we require immunization patient numbers for your facility by age group and eligibility status. This information is used to forecast our vaccine budget and determine appropriate order amounts and frequency for your facility.

VFC re-enrollment occurs every spring for all providers, but you should update your Provider Profile and Provider Agreement any time during the year if:

- Staff listed on the Provider Agreement changes

- Your contact information or vaccine shipping instructions change
- The number of immunization patients at your facility changes significantly
- Your facility type has changed (see bottom of page 1 of Provider Profile).

### ***Enrollment – New Providers***

Health care providers wishing to enroll in the VFC Program can begin by contacting the VFC Coordinator at the Montana Immunization Program by either telephone (444-0277) or email (hhsiz@mt.gov). The VFC Coordinator will briefly describe the program, learn about your facility, and determine whether you are a good fit for the VFC Program.

New provider enrollment involves the following steps:

- **VFC Enrollment Packet** – A VFC enrollment packet will be mailed to you prior to enrolling and contains information and forms pertaining to the VFC Program. Please review this material before your enrollment visit.
- **Enrollment Visit** – During an enrollment visit, a Montana Immunization Program staff member visits your facility, explains the VFC Program, inspects your vaccine storage equipment, and answers any questions you may have about the program. Ideally, enrollment visits are conducted in person, but depending on the circumstance, they may be done over the phone, through online video conferencing, or online video.
- **Submission of Provider Agreement and Provider Profile** – New providers must submit a Provider Agreement and Provider Profile (described above). Whenever possible, immunization patient numbers should be drawn from facility data or otherwise estimated. If you are a new facility with no patient records, leave this section of the profile blank.
- **Issuance of VFC#** – Once you have submitted your Provider Agreement and Provider Profile and have received an enrollment visit, your information will be entered into the VFC vaccine ordering system and you will be issued a VFC number that is unique to your facility. Your VFC number should be used on all correspondences pertaining to the VFC Program. Once you have a VFC number, you can place your first vaccine order (see Section 16 – Ordering and Receiving Vaccine in the *Vaccine Management Plan*).

Please note that the sequence and timing of VFC enrollment may vary depending on your location and availability of Immunization Program staff. Generally, VFC enrollment can be completed in two to four weeks.

### ***Inactivation***

Inactivation from the VFC Program is defined as a temporary suspension from vaccine ordering. Providers may request to be inactivated or the Montana Immunization Program may inactivate a provider for not complying with program requirements. Inactivation is considered a temporary situation, with the expectation that the situation warranting inactivation can be quickly remedied. Inactivated providers may be required to return all VFC vaccine per State instructions.

***Termination***

Termination from the VFC Program is the permanent removal of a provider from the program. Providers may choose to be terminated from the VFC Program or the Montana Immunization Program may terminate providers due to repeated non-compliance issues that have not been appropriately addressed by the provider or a permanent condition such as being listed on the “List of Excluded Individuals and Entities” (see Section 2 – Provider Enrollment). Terminated providers are required to return all VFC vaccine and State-supplied equipment per State instructions.

Termination from the VFC Program is considered permanent. However, a terminated provider may be allowed to re-enroll if they demonstrate full compliance and complete the enrollment process, including an enrollment site visit.

See Section 9 – Non-Compliance, Fraud, and Abuse for more details on program inactivation and termination.



### 3. BILLING

The main premise of the VFC Program is to supply vaccine at no charge to children who might not otherwise be vaccinated because of inability to pay.

There are two costs associated with VFC vaccine – the cost of the vaccine and the administration fee. The billing requirements of the VFC Program are statutorily defined as follows:



- Providers may not charge patients for VFC vaccine.
- Providers may bill an appropriate vaccine administration fee as long as it does not exceed \$14.13, the maximum regional charge set for Montana by the Centers for Medicare and Medicaid.
- At facilities that can serve the underinsured, private insurers cannot be billed for VFC vaccine but can be billed for the administration fee.
- VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

Please refer to the tables in Section 4 – VFC Eligibility for billing information under various VFC eligibility scenarios.

See “Borrowing” in Section 17, for options in correcting improperly billed vaccine.





## 4. VFC ELIGIBILITY

Funding for VFC vaccine is based on an estimate of VFC-eligible children in the state. In order to stay within budget, VFC vaccine must be given to eligible children only. Therefore, screening for eligibility is the foundation of accountability in the VFC Program. **VFC providers are required to screen patients for VFC eligibility at every immunization visit.**

Neglecting to screen for eligibility or knowingly administering VFC vaccine to unqualified patients may be grounds for termination from the VFC Program and may be investigated as fraud and abuse.



There are two steps to eligibility screening:

1. Determining the patient's eligibility status at each immunization visit (screening)
2. Documenting the screening results (documenting)

### ***Determining VFC Eligibility Status***

#### **Basic Eligibility Criteria**

Children through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:

- **Medicaid eligible:** A child who is eligible for the Medicaid program. (For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who have health insurance covered by a state Medicaid program.)
- **Uninsured:** A child who has no health insurance coverage
- **American Indian or Alaska Native (AI/AN):** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603)
- **Underinsured\*:** A child who has private health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only); or a child whose insurance caps vaccine coverage or annual visits at a certain amount. Once that coverage amount is reached, the child is categorized as underinsured.

\*Underinsured children are eligible to receive VFC vaccine only through Federally Qualified Health Centers<sup>1</sup> (FQHC) or Rural Health Clinics<sup>2</sup> (RHC).

<sup>1</sup> An FQHC is a health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide health care to a medically underserved population.

<sup>2</sup> An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area.

## Insured Children

Insured children are not eligible for the VFC Program. For purposes of the VFC Program, a child is considered insured if he or she has private health insurance that fully covers recommended immunizations or covers a portion of all recommended immunizations—even if some combination vaccines are excluded. Insured children are not eligible for the VFC Program even when claims for vaccination services are denied because of unmet deductibles.

## Special Eligibility Circumstances

In some situations, determining VFC eligibility status can be complicated. This section covers special eligibility situations sometimes encountered. In general, use the following guidelines when selecting between eligibility options:

- 1) Select the eligibility category that confers the least out-of-pocket expenses to the child's parent or guardian.
- 2) Select the eligibility category that is least likely to change.

## Healthy Montana Kids

Nationally, the Children's Health Insurance Program (CHIP) enables states to expand health insurance coverage for uninsured children. In Montana, CHIP is called Healthy Montana Kids. Healthy Montana Kids *Plus* is the State Medicaid program. For VFC eligibility purposes:

- Healthy Montana Kids children are considered insured.
- Healthy Montana Kids Plus children are Medicaid eligible.

VFC eligibility under these two programs is summarized in the table below.

**Table 1 VFC Eligibility for Healthy Montana Kids and Healthy Montana Kids Plus**

Population	VFC Provider Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee <sup>1</sup>
Healthy Montana Kids	Any	Insured	Ineligible	Private	Healthy MT Kids	Healthy MT Kids
Healthy Montana Kids Plus	Any	Medicaid	Medicaid	VFC	No charge	Medicaid

<sup>1</sup> VFC vaccine administration fees cannot exceed \$14.13 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

## Medicaid as Secondary Insurance

Any insured or underinsured child who has Medicaid as secondary insurance is eligible for the VFC Program.

Insured children with Medicaid as secondary are not required to participate in the VFC Program. The decision to participate should be based on what is most cost effective for the patient.

At private facilities, underinsured children with Medicaid as secondary should be designated “Medicaid” for VFC eligibility so they qualify for VFC vaccine. If marked as “underinsured,” they can only receive VFC vaccine at designated FQHC/RHC facilities.

**Table 2 VFC Eligibility for Children with Medicaid as Secondary Insurance**

Population	Facility Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee <sup>1</sup>
Medicaid as Secondary	Any	Insured/ Medicaid Secondary	Insured	Private	Insurer	Insurer <sup>2</sup>
			Medicaid	VFC	No charge	Medicaid
Medicaid as Secondary	FQHC/RHC	Underinsured/ Medicaid Secondary	Underinsured	VFC	No charge	Patient
			Medicaid	VFC	No charge	Medicaid
Medicaid as Secondary	Private	Underinsured/ Medicaid Secondary	Medicaid	VFC	No charge	Medicaid

<sup>1</sup> VFC vaccine administration fees cannot exceed \$14.13 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

<sup>2</sup> Reimbursement may be higher under this scenario, and Medicaid can be billed for the balance of unpaid administration fees up to \$14.13. If the primary insurer denies payment for the vaccine, VFC stock can be used to replace the private stock used (See Borrowing in Section 17).

### Family Planning Clinics

Unaccompanied minors less than 19 years of age who present at family planning clinics for contraceptive services or sexually transmitted disease (STD) treatment are considered uninsured and VFC-eligible if they do not know their insurance status due to the confidential nature of their visit. This special eligibility status is restricted to family planning clinics. Family planning clinics must track VFC vaccine given to patients in this eligibility category on a Family Planning Clinic Log and provide this information to the Montana Immunization Program upon request. The log can be found on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link.

### Incarcerated Juveniles

Incarcerated juveniles fewer than 19 years of age who lose access to their health insurance because of their circumstances are considered uninsured and VFC-eligible.

### Dual Eligibility – American Indians/Alaskan Natives

American Indians and Alaskan Natives (AI/AN) are often eligible for the VFC Program under more than one category. Please use the following table to determine VFC eligibility status, vaccine stock, and vaccine billing for AI/AN populations seen at providers *other than* Indian Health Service (IHS) facilities.

**Table 3 VFC Eligibility for American Indian and Alaskan Native Populations**

Population	Facility Type	Insurance Status	VFC Eligibility Category	Vaccine Stock	Bill to:	
					Vaccine	Administration Fee <sup>1</sup>
AI/AN	Any (except IHS)	Medicaid	Medicaid	VFC	No charge	Medicaid
AI/AN	Any (except IHS)	Uninsured	AI/AN	VFC	No charge	Patient
AI/AN	Private	Underinsured	AI/AN	VFC	No charge	Patient
AI/AN	FQHC/RHC	Underinsured	AI/AN	VFC	No charge	Patient
AI/AN	Any (except IHS)	Insured	Eligible <sup>2</sup>	Private	Insurer	Insurer
				VFC	No charge	Insurer

<sup>1</sup> VFC vaccine administration fees cannot exceed \$14.13 (See Section 3 – Billing). VFC vaccinations cannot be denied to an established VFC-eligible patient due to the inability of the parent or guardian to pay the administration fee.

<sup>2</sup> Insured AI/AN children are not required to participate in the VFC Program. The decision whether to participate should be based on what is most cost effective for the patient. However, we encourage providers to use private stock on fully insured patients.

## Documenting Eligibility Screening

Eligibility screening must occur at every immunization visit. Documenting the screening results is required under the following circumstances:

- At the first immunization visit in the calendar year
- Whenever VFC eligibility status changes.

Eligibility screening records must be kept for three years and made available to Montana Immunization Program staff on request and during site visits.

The Montana Immunization Program accepts four methods for documenting eligibility screening:

- 1 **State-Supplied Eligibility Form** – These forms are available on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov). The instructions for using the form are on the back of the sample. This form captures three categories of information at each immunization visit: patient information, eligibility status, and vaccine doses administered. Document the patient's eligibility status at the first immunization visit each calendar year by placing a checkmark in the appropriate category. On subsequent visits, you will leave the eligibility status section blank, unless the patient's status has changed. All other information should be recorded for each immunization visit. There are four different versions of this form, each of which takes into account the different eligibility statuses and vaccine offerings at public, private, and specialty clinics. Be sure to use the form that best suits your practice.
- 2 **WIZRD (Immunization Information System)** – The second option for documenting eligibility screening is through WIZRD, the Montana web-based immunization information system (IIS). This online program records patient immunization records, manages vaccine inventory, and documents eligibility status.

WIZRD is available to all VFC providers free-of-charge. Instruction on the use of WIZRD is beyond the scope of this handbook. If you would like more information, please contact the Montana Immunization Program (444-5580 [hhsiz@mt.gov](mailto:hhsiz@mt.gov)).

- 3 **Clinic Computer-Generated Report** – The third approved method for documenting VFC eligibility status is to use your clinic charting or billing system to generate a custom report. The report must meet certain criteria and be approved by the Montana Immunization Program before use. The criteria for approval and instructions for submitting a report for review are found on the Request Form for Clinic Computer Report found on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link.
- 4 **Comprehensive Screening Form** – The last option for documenting VFC eligibility screening applies to providers whose client base is exclusively American Indian or Alaskan Native. These providers can submit a comprehensive screening form once per year during their enrollment. Submission of this form releases them from having to screen for eligibility at each immunization visit.

Contact the Montana Immunization Program if you would like additional information about eligibility screening and documentation options – 444-5580 [hhsiz@mt.gov](mailto:hhsiz@mt.gov) .



## 5. ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

The ACIP is a federal advisory committee that recommends routine immunization practices for children and adults in the US.

The major functions of the ACIP are to:

- Develop technical recommendations on vaccine use and immunization practices
- Harmonize immunization schedules with those of other advisory groups such as the American Academy of Pediatrics and the American Academy of Family Physicians
- Approve vaccines for use in the VFC Program.

After approval, ACIP recommendations are published in *Morbidity and Mortality Weekly Report* (MMWR), a scientific periodical prepared by the CDC (<http://www.cdc.gov/mmwr/>) and become the standard of practice for administering the applicable vaccines.

### **VFC Resolutions**

Once a new or amended recommendation is published, the ACIP approves it for inclusion in the VFC Program by passing a VFC resolution. VFC resolutions determine what vaccines are available through the VFC Program, including the dosage and schedule. VFC resolutions are the rules that providers must follow when administering vaccines under the VFC Program.

The CDC publishes current VFC resolutions on their website at <http://www.cdc.gov/vaccines/programs/vfc/acip-vfc-resolutions.htm>.

A current list of vaccines provided by the Montana VFC Program can be found at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the “VFC” link, document title “Available VFC Vaccines.”

Please note the following about VFC resolutions:

- VFC resolutions may not be identical to published ACIP recommendations.
- An ACIP recommendation does not apply to the VFC Program until the VFC resolution is approved.
- For new recommended vaccines, a VFC resolution must be approved before the CDC can negotiate a purchase contract with the manufacturer. Therefore, there may be a delay between when the resolution is approved and when the vaccine is available.

The Montana Immunization Program monitors ACIP recommendations and VFC resolutions and ensures that the Montana VFC Program reflects current guidance. As a VFC provider, you will be notified when new and amended ACIP recommendations and VFC resolutions become available.

### **ACIP Recommendations – Exceptions**

Health care professionals can deviate from ACIP recommendations under the following circumstances:

- They deem in their medical judgment and in accordance with accepted medical practice that compliance with ACIP recommendations is medically inappropriate
- The particular requirement contradicts State law pertaining to religious or medical exemptions.



## 6. NATIONAL CHILDHOOD VACCINE INJURY ACT REQUIREMENTS (NCVIA)

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to



vaccinations. Health care professional who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations. Please note that these requirements apply to ALL vaccinations administered at your facility, not just those given through the VFC Program.

### ***Vaccine Information Statements (VIS)***

VISs are published by the CDC and provide information to vaccine recipients about the risks and benefits of each vaccine. **You must provide a current vaccine-specific VIS to your patient or your patient's legal guardian at each vaccination visit.**

VISs are updated periodically, and the CDC maintains the current print, audio, and foreign language versions on their website at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>.

We recommend storing all VISs in one location and designating one person responsible for updating them. The CDC VIS webpage (link provided above) offers a "Get email updates" function whereby you are notified through email when VISs have been changed so you are prompted to update your stock.

### ***Vaccine Adverse Event Reporting System (VAERS)***

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide mechanism through which adverse events following immunization can be reported, analyzed, and made available to the public. The VAERS website is <http://vaers.hhs.gov/professionals/index>.

### **Reportable Events – Required**

The NCVIA requires health care providers to report:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination.

**Reportable Events – Voluntary**

You may report any adverse event that occurs after the administration of a vaccine licensed in the US. You may report adverse events even if you are unsure whether a vaccine caused them.

***Vaccine Charting Requirements***

The NCVIA requires that vaccination records be included in a patient's permanent medical record and that they include the following information:

- Name of the vaccine
- Date of vaccine administration
- Vaccine manufacturer and lot number
- Name and title of the person giving the vaccine
- Address of the clinic where vaccine was given
- Publication date of the VISs and date it was provided to the patient.

A number of resources are available for charting records. The Immunization Action Coalition website (<http://www.immunize.org/handouts/document-vaccines.asp>) provides free immunization charts that capture all the information required by the NCVIA.

## 7. VFC COMPLIANCE SITE VISITS

### **Overview**

The CDC requires the Montana Immunization Program to periodically visit VFC providers to assess compliance with program requirements. These visits are called VFC compliance site visits or simply “site visits.”



The goal of the Montana Immunization Program is to ensure provider compliance through effective communication, and a site visit should be considered more of an educational opportunity than an “audit.” Most VFC Program compliance issues are addressed through education. Only cases of repeated and intentional non-compliance progress to advanced stages of corrective action. Please refer to Section 9 for more details on how non-compliance, fraud, and abuse are handled in the Montana VFC Program.

### **Self Assessment**

We encourage you to continuously assess your VFC compliance, especially prior to your site visit, by using the checklist in Section 8 – VFC Program Requirements. This list details the main requirements of the VFC Program and references sections of this handbook for more information.

### **Site Visit Process**

VFC providers in Montana can expect a site visit from the Montana Immunization Program **every other year**, typically in the spring, summer, or early fall.

VFC site visits are usually combined with another assessment function of the Montana Immunization Program—AFIX visits, where facility immunization rates are determined through chart reviews (AFIX procedures are not covered in this handbook). The general procedure for combined VFC/AFIX site visits is outlined below (AFIX-specific steps are indicated in parentheses.):

### **Site Visit Preparation**

1. Approximately one month prior to your visit, a Montana Immunization Program staff member will contact you by telephone or email to schedule the visit.
2. After the visit is scheduled, you will receive a letter confirming the site visit date and requesting an active patient list (AFIX).

3. After reviewing your active patient list, the Immunization Program will fax or email you a list of charts that will be reviewed during your site visit (AFIX).

### During the Site Visit

4. Site visits can take from 1 to 4 hours depending on the size of your clinic, the number of charts to review, and the educational opportunities that arise.
5. Please make the following available during the visit:
  - a. The vaccine manager and any key staff involved in the VFC Program
  - b. A work space large enough for a laptop computer and charts
  - c. Three months of temperature logs from your vaccine storage units
  - d. Your completed and annually reviewed *Vaccine Management Plan*
  - e. VFC eligibility screening documentation
  - f. Charts requested in Step 3 above (AFIX).
6. Approximately one hour of the site visit will be one-on-one with your vaccine manager. Immunization Program staff will ask questions pertaining to the practices at your facility for implementing the VFC Program. They will also inspect your vaccine storage units.
7. After the one on one with the vaccine manager, the Immunization Program staff can work independently as they review charts and enter data into their computer.
8. At the end of the visit, you will receive feedback on your compliance with the VFC Program including areas of strength, areas for improvement, and any corrective actions.

### Site Visit Follow-Up

9. Approximately one month after your site visit, you will receive a follow-up letter from the Immunization Program detailing the results of your VFC/AFIX visit. It will reiterate any VFC compliance issues and corrective action plans mentioned during your site visit.
10. In order to remain in good standing with the VFC Program, you are responsible for carrying out any corrective actions recommended by the Montana Immunization Program. Immunization Program staff may follow up by telephone and email.
11. Immunization Program staff may ask to return to your facility for an educational site visit to address VFC non-compliance and AFIX issues.

### Other Visits from the Montana Immunization Program

- **Educational Visits** – Educational visits are those where the main purpose is education and not assessing compliance.
  - **Provider Request** – Providers may request an educational visit from the Montana Immunization Program at any time. Educational visits are useful when there has been a change in staff,

- location, or management. Education visits are dependent on availability of Immunization Program staff and can also be conducted by telephone.
- Non-Compliance Response – An educational visit may occur in response to provider non-compliance. The visit will focus on correcting the specific compliance issue.
  - **Enrollment Visits** – Enrollment visits occur during the enrollment process, See Section 2 – Provider Enrollment for more information on VFC Program enrollment.



## 8. VFC REQUIREMENT CHECKLIST

Below is a checklist of VFC requirements by frequency that can be used to assess your compliance with the program.



**Table 4 VFC Requirement Checklist by Frequency**

X	VFC Requirement by Frequency	More Information
<b>Once (upon enrollment or as needed)</b>		
	Set up vaccine storage units/thermometers according to the <i>Vaccine Management Plan</i>	Section 13
	Post “DO NOT UNPLUG” signs on outlets and circuit breakers serving vaccine storage units	Section 13
	Fill-in Section 12 of the <i>Vaccine Management Plan</i> . Copy and post on vaccine storage units. Review <i>Vaccine Management Plan</i> with staff.	Sections 11,12
<b>Every Vaccination Visit</b>		
	Screen for VFC eligibility – Document at first visit in the calendar year and when status changes	Section 4
	Distribute Vaccine Information Statement to patient (VIS)	Section 6
	Chart required vaccination information	Section 6
<b>Twice Daily</b>		
	Log temperatures and Data Logger LED status for each storage unit	Sections 13,14
<b>Monthly (by the 5<sup>th</sup> of every month)</b>		
	Download and save Data Logger (thermometer) data	Section 14
	Submit Monthly Vaccine Report to Home IV Pharmacy	Section 15
	Order vaccine (if needed) through Home IV Pharmacy	Section 16
<b>Yearly</b>		
	Review <i>Vaccine Management Plan</i> with staff and update/re-post Section 12, if necessary	Section 11-17
	Re-enroll by submitting Provider Profile and Provider Agreement (per State instructions)	Section 2
<b>Every Other Year</b>		
	Host a compliance site visit from the Montana Immunization Program	Section 7
<b>As Needed</b>		
	Submit Wasted and Expired Vaccine Report	Section 17
	Submit Vaccine Incident Report	Section 13
	Fill out Vaccine Storage Trouble-Shooting Log (Page 3 of temperature logs)	Section 13
	Submit VAERS incidents	Section 6
	Document borrowing on VFC Vaccine Borrowing Report	Section 17
	Update and re-post Section 12 of the <i>Vaccine Management Plan</i> if information changes	Sections 11, 12
	Retain VFC documentation for three years, including eligibility screening documents, temperature logs, monthly reports, borrowing forms, and any forms or reports specific to your facility.	Sections 4,14





## 9. NON-COMPLIANCE, FRAUD, AND ABUSE

By signing the Provider Agreement, you are agreeing to abide by the statutory requirements of the program.

These requirements are federal law, and as the administrator of the VFC Program in Montana, the Immunization Program must enforce compliance.

Non-compliance, fraud, and abuse is typically discovered during VFC site visits but may also be self-reported, reported by third parties, or revealed through vaccine ordering and accountability data. All circumstances are unique making it difficult to develop a set of rules for handling all situations. We also recognize our obligation to communicate effectively to providers about VFC Program requirements.

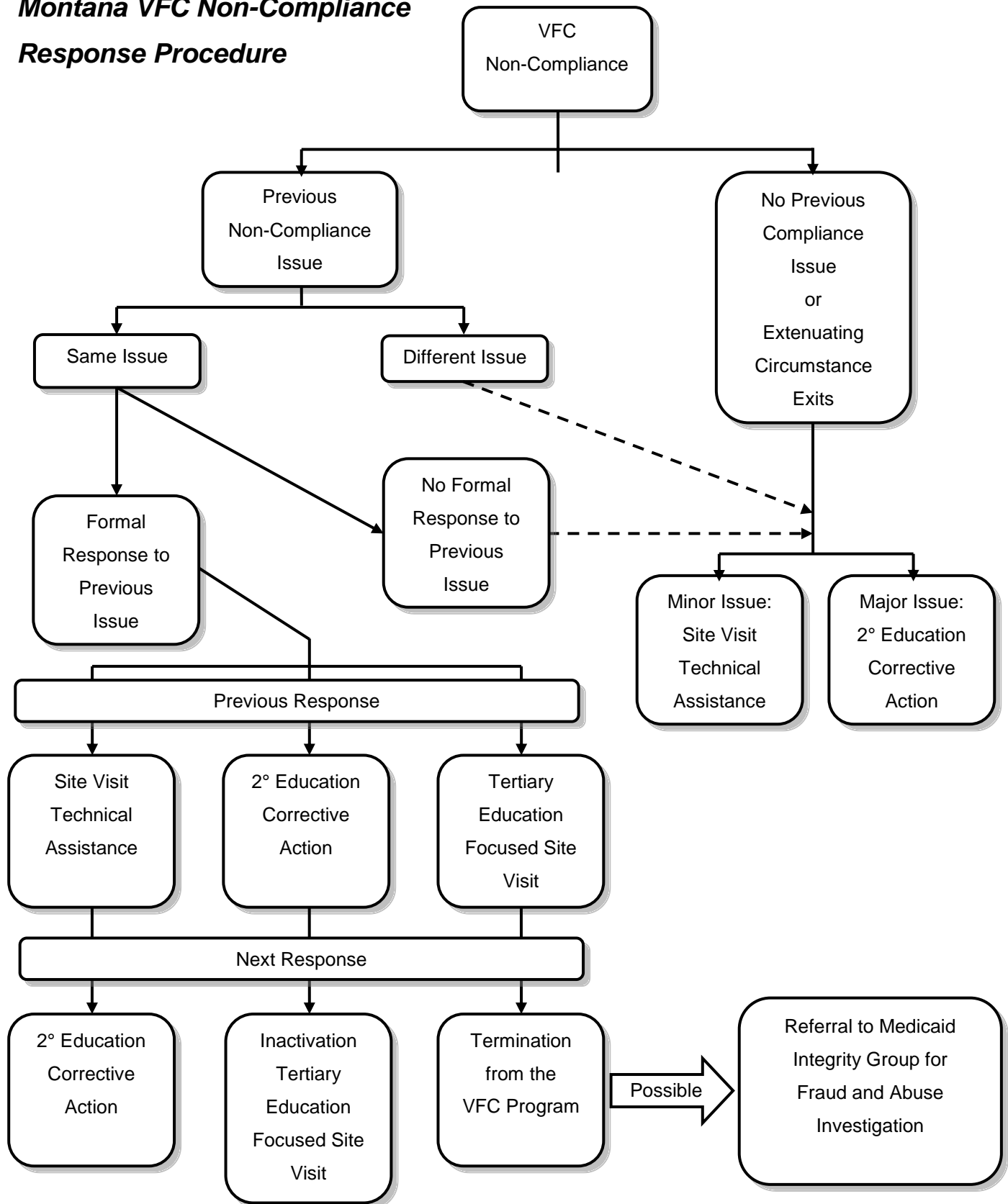
### *Policy*

The primary response of the Montana Immunization Program to non-compliance, fraud, and abuse is education, which progresses through three levels as defined below:

- **Site Visit Technical Assistance** – Site visit technical assistance occurs when minor compliance issues are corrected during a site visit and no corrective action from the provider is required. If subsequent follow up indicates that the issue has not been corrected, the compliance issue progresses to the secondary education level.
- **Secondary Education** – Secondary education focuses on a specific non-compliance issue and includes a corrective action plan for the provider. Secondary education can occur in person during a regular compliance site visit but may occur via telephone or email. If the corrective action plan is not completed and/or the issue is not corrected, providers are inactivated from vaccine ordering, and the issue progresses to the tertiary education level.
- **Tertiary Education** – Tertiary educational involves a focused site visit directed at a specific non-compliance issue and a corrective action plan for the provider. If the corrective action plan is not completed and/or the issue is not resolved at this level, the provider is terminated from the VFC Program and possibly referred to the Medicaid Integrity Group for investigation for fraud and abuse.

In general, providers are given three opportunities to correct non-compliance issues before being inactivated or terminated from the VFC Program. When responding to non-compliance issues, the Immunization Program will consider extenuating circumstances, whether it is a major or minor issue, and whether the non-compliance is intentional, negligent, or simply an error due to lack of knowledge. The basic process for Montana VFC non-compliance response is outlined in the diagram on the next page.

## Montana VFC Non-Compliance Response Procedure



## ***Definitions***

**Abuse** – Provider practices that are inconsistent with sound fiscal, business, or medical practices that result in an unnecessary cost to the Medicaid program, immunization program, a health insurance company, or a patient; or reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

**Corrective Action Plan** – Tasks that must be completed by the provider in order to resolve a noncompliance issue. Corrective action plans are part of secondary and tertiary education sessions.

**Extenuating Circumstance** – A condition that makes a non-compliance issue excusable or less serious.

**Focused Site Visit** – An in-person visit from Immunization Program staff that educates a provider on a specific non-compliance issue and ensure that corrective actions have taken place. A focused site visit is separate from a compliance site visit.

**Follow-Up** – Actions taken by the Immunization Program staff to ensure that a corrective action has taken place and a compliance issue is resolved.

**Fraud** – An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person.

**Inactivation** – Temporary suspension of vaccine ordering in the VFC Program. Inactivated providers may be required to return VFC vaccine per State instructions.

**Intentional** – Acting with full awareness of what one is doing and the consequences of the action.

**Major Issue** – A provider action that results in non-compliance with one of the statutorily defined requirements outlined in the VFC Provider Agreement. (e.g., neglecting to document eligibility screening.)

**Medicaid Integrity Group** – A division of the Centers for Medicare and Medicaid Services charged with investigating fraud, waste, and abuse in the Medicaid program.

**Minor Issue** – A provider action, oversight, or mistake that minimally affects compliance with a VFC requirement. (e.g., having an outdated VIS in your VIS supply.)

**Negligent** – Acting careless, inattentive, neglectful, willfully blind, or reckless.

**Non-Compliance** – Failure to meet all or part of the requirements of the VFC Program.

**Termination** – Permanent removal of a provider from the VFC Program. Terminated providers are required to return all VFC vaccine per State instructions.



## 10. IMMUNIZATION RESOURCES

### **State**

Immunization Program: 444-5580; fax 444-2920

Immunization Program website: <http://immunization.mt.gov>

Immunization Program Manager: Lisa Underwood 444-0065

Office Manager: Katie Grady 444-5580

### **VFC**

VFC Coordinator/Vaccine Manager: Lori Hutchinson 444-0277

To report VFC Fraud and Abuse: 444-0277

Vaccine Ordering: Home IV Pharmacy 723-4099, fax 723-4059, 2601½ Continental Drive, Butte, MT 59701

CDC Public Health Advisor: Carolyn Parry 444-2675

### **Other State Programs**

Adolescent and Adult Immunization Coordinator: Laura Baus 444-6978

Distance Learning Coordinator and Daycare Coordinator: Lori Rowe 444-2969

Perinatal Hepatitis B Coordinator/Nurse Consultant: Susan Reeser 444-1805

School Assessment Coordinator: Tim Horan 444-1613

### **Immunization Information System - WIZRD**

Immunization Information System (IIS) Manager: Bekki Wehner 444-9539

IIS Training and Support: Jennifer Hepner 444-4560

WIZRD password resets: 444-9500

WIZRD website: <https://wizrd.hhs.mt.gov/wizrd/index.htm>

### **Federal**

Centers for Disease Control and Prevention (CDC) website: <http://www.cdc.gov/>

CDC Vaccines and Immunizations website: <http://www.cdc.gov/vaccines/>

Vaccine Information Statements (VIS): <http://www.cdc.gov/vaccines/pubs/vis/default.htm>

Immunization Information: (800) 232-4636 English and Spanish

CDC Vaccine Safety website: <http://www.cdc.gov/vaccines/vac-gen/safety/default.htm>

Vaccine Adverse Event Reporting System (VAERS): <http://vaers.hhs.gov/index>

## ***Other:***

Immunization Action Coalition (IAC): (651) 647-9009

IAC produces a newsletter called Needle Tips

Vaccine Information Statements (VIS) are available in English and many foreign languages.

IAC website: <http://www.immunize.org/>

National Network for Immunization Information (NNii): (409) 772-0199

NNii website: <http://www.immunizationinfo.org/>

Pharmaceutical Companies:

GlaxoSmithKline	(866) 475-8222	<a href="http://www.gsk.com/products/vaccines/index.htm">http://www.gsk.com/products/vaccines/index.htm</a>
MedImmune	(877) 633-4411	<a href="http://www.medimmune.com">http://www.medimmune.com</a>
Merck & Co.	(800) MERCKRX	<a href="http://www.merckvaccines.com">http://www.merckvaccines.com</a>
Novartis	(800) 244-7668	<a href="http://www.novartisvaccines.com">http://www.novartisvaccines.com</a>
Pfizer (Wyeth)	(800) 666-7248	<a href="http://www.wyeth.com/vaccines">http://www.wyeth.com/vaccines</a>
sanofi pasteur	(800) VACCINE	<a href="http://www.vaccineshoppe.com">http://www.vaccineshoppe.com</a>

## ***VFC Forms***

The following forms are found under the VFC link on the Montana Immunization Program website at [www.immunization.mt.gov](http://www.immunization.mt.gov):

- Vaccine Order Form
- Monthly Vaccine Report (public and private provider versions)
- Eligibility Screening Forms (multiple clinic-specific versions)
- Wasted and Expired Vaccine Report
- Borrowing Form
- Temperature Logs and Storage Unit Trouble-Shooting Logs
- Vaccine Incident Report
- Request Form for Clinic Computer Report

Not all VFC forms are provided on our website. Please contact the Montana Immunization Program if you have difficulty finding a form (444-5580 [hhsiz@mt.gov](mailto:hhsiz@mt.gov)).

# **Vaccine Management Plan**





## 11. VACCINE MANAGEMENT PLAN – INTRODUCTION

Vaccines are fragile and expensive, and proper storage and handling practices are critical to providing effective immunizations. The CDC requires VFC providers to have a written vaccine management plan, and Sections 11–17 of this handbook serve this function. When you sign the VFC Provider Agreement each year, you are agreeing to abide by the vaccine management practices outlined in this plan.

### ***Customizing this Plan for Your Facility***

Designating a vaccine manager (and alternate) and developing an emergency plan are two critical components to vaccine management. You are required to customize this plan for your facility by documenting this information in Section 12.

#### **To customize this plan for your facility:**

1. Fill-in Section 12 starting on page 43. You can hand-write the information or use a computer editable version of Section 12 found on our website ([www.immunization.mt.gov](http://www.immunization.mt.gov)).
2. Review the entire *Vaccine Management Plan* (Sections 11–17) with staff involved in the VFC Program.
3. Document the review in the table in Section 12, page 43.
4. Post a copy of Section 12 on each VFC vaccine storage unit.
5. Update and re-post Section 12 as necessary so that the information is accurate.

#### **Every year:**

6. Review the entire *Vaccine Management Plan* with staff. Update Section 12, if necessary.
7. Document the annual review in the table on page 43.
8. Re-post a copy of Section 12 on each VFC vaccine storage unit.
9. Retain for three years any old versions of Section 12 that document past reviews/updates.

**We will assess compliance with these requirements during your VFC site visit.**



## 12. EMERGENCY PLAN

Use the information in this section to respond to emergencies that threaten your vaccine supply. Customize your plan by filling in the information below and posting a copy of this section (Section 12) on each vaccine storage unit. A stand-alone version of this section that can be edited on a computer is available on our website under the VFC link ([www.immunization.mt.gov](http://www.immunization.mt.gov)).

### ***Provider Information***

Enter provider-specific VFC information below

Provider/Facility Name	VFC #
------------------------	-------

### ***Designated Vaccine Manager***

Designate one person primarily responsible for vaccine management and one alternate responsible person for when the primary is not available. A second alternate is optional.

Vaccine Manager (Primary person responsible for vaccine management)	Phone
Alternate Vaccine Manager (Person responsible for vaccine management when primary is unavailable)	Phone
Second Alternate Vaccine Manager (Optional) (Person responsible for vaccine management when primary and alternate is unavailable)	Phone

### ***Vaccine Management Plan Review***

Review your *Vaccine Management Plan* annually and anytime you have a change in staff. Update this section (Section 12), if necessary. Document reviews and updates below by listing the date, circling whether it was a review, update or both, and listing the initials of the staff involved.

Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials
Update/Review Date	Staff Initials	Update/Review Date	Staff Initials

## ***Emergency Power Outage Plan***

### **Backup Generator**

Does your facility have a backup generator?

☐ Yes (Provide contact information below) ☐ No (Provide alternate vaccine storage locations, next section).

Contact person for generator maintenance	Phone
--	-------

### **Alternate Vaccine Storage Locations**

If you have no backup generator, identify at least one alternate vaccine storage facility that has proper refrigerator and freezer units, temperature monitoring capabilities, and backup power where vaccine can be stored in the event of a power outage. Designate two locations, if possible.

Alternate Location #1	Contact Name	Phone
Alternate Location #2 (Optional)	Contact Name	Phone

## ***Emergency Phone Numbers***

As appropriate for your facility, provide the phone numbers listed below:

Utility Company	Phone
Building Maintenance	Phone
Building Alarm Company	Phone
Refrigerator/Freezer Repair	Phone
Backup Generator Repair	Phone
Dry Ice Vendor	Phone
Vaccine Transport	Phone
Other -	Phone

## ***Packing and Transporting Vaccine***

### **Emergency Packing Supplies**

To prepare for an emergency, store the following supplies at your facility in the location designated below.

Quantities should be sufficient to handle your entire vaccine supply.

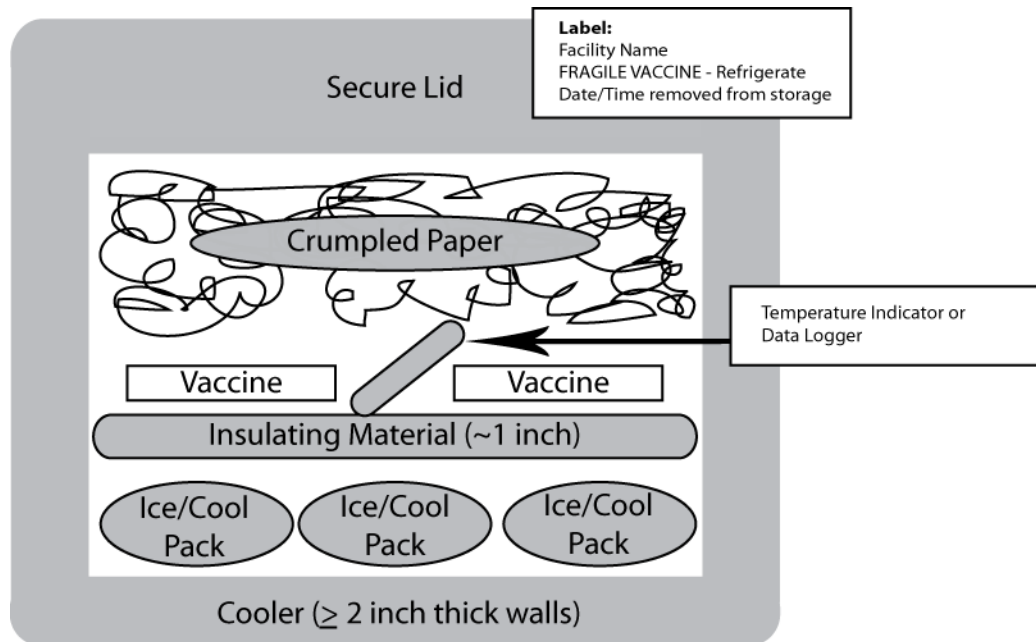
Location of Emergency Packing Supplies
--

- Insulated coolers with  $\geq 2$  inch thick walls (separate coolers for refrigerated and frozen vaccines)
- Cool packs (refrigerated), 2–3 per cooler
- Ice packs (frozen), 2–3 per cooler
- Dry ice, at least 6 pounds for each cooler transporting frozen vaccine (Dry ice is usually not stored on site, but identify a nearby vendor, if possible.)
- Temperature indicators or Data Loggers from your storage units
- Insulating material (e.g., cardboard, crumpled paper, bubble wrap, Styrofoam)
- Flashlight with spare batteries

### **Vaccine Packing Procedure**

- Contact your alternate vaccine storage location to confirm transfer.
- Do not open storage unit doors until coolers are prepared and ready to receive vaccine.
- Keep vaccine in original boxes when packing in coolers.
- Diluent packaged separately from vaccine should be transported in refrigerated coolers or at room temperature. Diluent packaged with vaccine should remain with vaccine during transport.
- Record the date/time and temperature of vaccine storage units at the time you remove the vaccine for transport.
- Prepare transport coolers as follows:
  - **Refrigerated Vaccine (See Figure 1)**
    - Pack refrigerated vaccine first.
    - Maintain refrigerated vaccine between 35° – 46°Fahrenheit (F) (2° – 8°Celsius (C)).
    - Place ice packs (summer)) or cool packs (winter) in the bottom of the cooler followed by an approximately 1-inch layer of insulating material such as cardboard, crumpled paper, bubble wrap, or Styrofoam.
    - Place the vaccine and a temperature monitor or Data Logger on top of the insulated material making sure that the vaccine does not touch ice packs or cool packs. In summer, a second layer of insulating material on top of the vaccine followed by ice packs may be required.

- Fill the remaining open space at the top with crumpled paper or insulating material to prevent the vaccine from shifting while in transport.
- Close and secure the lid.
- Label the container with your facility name and “Fragile Vaccines – Refrigerate” and the date and time the vaccine was removed from the permanent storage unit.



**Figure 1 Packing Refrigerated Vaccine for Transport**

- **Frozen Vaccine**

- Pack frozen vaccine in a separate cooler from refrigerated vaccine.
- Maintain frozen vaccine at or colder than 5°F (-15°C).
- Pack frozen vaccine and a temperature monitor or Data Logger with at least 6 pounds of dry ice per container. No barrier material is necessary, but keep vaccine in original boxes.
- If dry ice is not available, use ice or cool packs with no barrier material. Vaccine must be used within 72 hours if the temperature is not maintained at or below 5°F (-15°C) during transport.
- Label the container with your facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.

## **During Transport**

- Avoid prolonged temperature extremes by transporting containers inside vehicles and taking the quickest route possible. Do not leave vaccine unattended in vehicles during very hot or very cold weather.

## **While in Alternate Storage**

- Monitor storage unit temperatures twice daily.
- If vaccine viability is in question, segregate the affected vaccine and mark “Do Not Use, contact the Montana Immunization Program (444-5580), and obtain a Vaccine Incident Report. Follow the procedure on the report to determine vaccine viability.

## 13. VACCINE STORAGE UNITS

The following information outlines the storage unit requirements of the Montana VFC Program.

### ***General Requirements***

Refrigerators and freezers used for storing VFC vaccine must (*VFC Operations Guide*, M-6, page 8):

- Maintain required vaccine storage temperatures year-round:
  - Refrigerator: 35° to 46°F (2° to 8°C)
  - Freezer: 5°F or colder (-15°C or colder)
- Hold the year's largest inventory plus ice packs (freezer) and water bottles (refrigerator) to stabilize temperatures
- Have a working National Institute for Standards and Testing (NIST)- or American Society for Testing and Materials (ASTM)-calibrated thermometer inside each storage compartment (See Section 14)
- Be dedicated to vaccine storage (Food and beverages are not allowed in vaccine storage units.)

### ***Combined Versus Stand-Alone Units***

Two types of storage units are acceptable:

- Combined refrigerator/freezer units that have separate external doors for each compartment
- Stand-alone refrigerators and freezers

Combined units are those that have a refrigerator and freezer compartment in one appliance. Stand-alone units have just one compartment that is either a refrigerator or freezer. In general, stand-alone units are a better choice for vaccine storage because they are better able to maintain proper vaccine storage temperatures

### ***Dormitory-Style Storage Units***

Dormitory-style (also called “bar-style”) refrigerator/freezer units are those where the freezer is contained within the refrigerator, and both are accessed by one external door. Please note that the term “dormitory-style” does not refer to the size of the unit. It refers to the location of the freezer within the refrigerator compartment. These units cannot reliably maintain vaccine storage temperatures. The CDC prohibits the use of dormitory-style storage units for the *permanent* storage of VFC vaccine.



**Figure 2 Dormitory-  
Style  
Refrigerator/Freezer**

## Policy on Dormitory-Style Storage Units:

- Beginning with the 2011 re-enrollment, which occurs in April, VFC providers are prohibited from using dormitory-style storage units for permanent storage of VFC vaccine.
- Permanent storage is defined as that involving more than one day's supply of vaccine for longer than one daily work shift (12 hours).
- The practice of using dormitory-style units for *temporary* storage of VFC vaccine is allowed for those providers already using the units in this capacity (as of February 1, 2011) and as long as certain conditions are met.
- Temporary storage is defined as that where only one day's supply of vaccine is stored for one workday (no more than 12 hours). Vaccine is returned to permanent storage at the end of the day.
- Providers wishing to continue to use dormitory-style units for temporary storage of VFC vaccine must agree to certain conditions and obtain written approval from the Montana Immunization Program. Please contact the Immunization Program for more information.
- VFC vaccine storage units acquired for VFC vaccine after February 1, 2011 must not be dormitory-style units regardless of whether they are used for temporary or permanent storage.

## Domestic Grade

Domestic (or "household") quality storage units are those typically found in homes and sold at retail appliance stores. Domestic grade appliances can be used to store VFC vaccine as long as combined refrigerator/freezer units have a separate external door for the refrigerator and freezer compartments and are not dormitory-style units (See *Dormitory-Style Units* above).

Other desirable features include:

- Separate temperature controls for refrigerator and freezer
- Automatic defrost cycling (i.e., "frost-free")
- Fully adjustable shelves
- Door locks
- Door ajar alarm
- Battery back-up

Undesirable features include:

- Manual defrosts—These units accumulate frost and ice on the walls of the freezer and cooling coils, and require periodic "defrosting." If you have a manual defrost unit you must arrange alternate vaccine storage and temperature tracking while you defrost your appliance.
- Single-thermostat units—These are combined units with a single thermostat dial that controls both the refrigerator and the freezer. This configuration makes it difficult to maintain appropriate temperatures in both compartments and increases the likelihood of freezing vaccine in the refrigerator. **Please note** that The Montana Immunization Program does not prohibit the use of single-thermostat units. However, such



units should be monitored carefully. If temperature excursions and vaccine waste occur, you will be required to upgrade to a dual temperature control model.

## ***Laboratory/Pharmacy-Grade***

Laboratory- or pharmacy-grade refers to storage units that are specifically designed to store vaccine and pharmaceuticals in a laboratory or pharmaceutical setting. These are the highest quality option for storing VFC vaccine. Laboratory-grade appliances come with safety, temperature control, and security options typically not found on domestic units. Although usually more expensive, they come in a wide variety of sizes, configurations, and prices, including moderately priced under-counter models ideally suited for small clinics.

## ***Size Determination***

Your VFC vaccine storage unit must be able to store the year's largest supply of vaccine including ice packs and water bottles used to stabilize temperatures. It also must be large enough to allow spacing between vaccine packages for proper air circulation (See Vaccine Placement, page 51).

To determine the size storage unit you need, calculate the largest number of doses you will have on hand during the year for both your refrigerator and freezer. Be sure to include seasonal influenza and private stock if it will all be stored in the same unit. Multiply the maximum doses by 1.25 to account for package spacing. Use this number (maximum doses) and the chart below to determine the minimum cubic feet of storage space you will need.

**Table 5 Minimum Cubic Feet of Storage Space Based on Maximum Doses**

Refrigerator		Freezer	
Maximum Doses	Minimum Cubic Feet Required	Maximum Doses	Minimum Cubic Feet Required
1001–2000	40	501–6000	7–14.8
900–1000	36	201–500	5–5.6
801–900	21–23	0–200	3.5–4.9
701–800	17–19.5		
401–700	11–16.7		
100–400	4.9–6.1		

## ***Setting Up your Storage Unit***

Follow the procedures below when acquiring a new storage unit, moving an existing unit, or reestablishing a unit after a power outage or repair.

## Unit Placement

- Place the unit close to a reliable electrical outlet (See *Electrical Supply* below).
- For proper cooling and heat exchange, locate the storage unit in a well-ventilated space away from direct sunlight and with 4 inches between the unit and surrounding walls, cabinets, and appliances.
- Do not block the motor compartment, which is usually located in the back or side of the unit.

## Electrical Supply

- Place the storage unit near enough to an outlet so that the cord is not a tripping hazard and an extension cord is not necessary.
- Make sure the outlet is not controlled by a light switch.
- Place a “DO NOT UNPLUG” sign next to the outlet **and its controlling circuit breaker**. If these are not accessible or visible, place the sign as near as possible so that anyone accessing the outlet or circuit breaker is likely to see it.
- If possible, do not plug more than one appliance into the outlet to avoid tripping the circuit breaker.
- If you have a backup power supply for your facility, make sure it is in working order and tested regularly.
- If you do not have a backup power supply, arrange at least one alternate vaccine storage location that has proper refrigerator and freezer units, temperature monitoring capability, and backup power where your vaccine can be moved in the event of a power outage. Record this information in Section 12 of this document.

## Temperature Stabilizing

- Plug the unit into the electrical outlet and set the temperature to fall within the following ranges:
  - Refrigerator: 2° to 8°C (35° to 46°F)
  - Freezer: -15°C or colder (5°F or colder)
- If the unit has a thermostat, set to the following target temperatures:
  - Refrigerator: 4°C or 40°F
  - Freezer: -20°C or -5°F
- If the unit has a controller with numbers or words (e.g., “colder”), set as follows:
  - Refrigerator: Set slightly warmer than mid-range.
  - Freezer: Set to mid-range.

**Please note** – For most numbered temperature dials, the higher the number the colder the temperature. Check your owner’s manual to avoid improper adjustments.

- Place a working NIST- or ASTM-calibrated thermometer inside each storage compartment in a central location away from walls, vents, fans, and cooling coils. The Montana Immunization Program has a supply of thermometers for VFC providers (see Section 14).
- Place several containers of water along the inside walls, in door racks, and vegetable bins (“crispers”) of the refrigerator, and several frozen packs along the walls and in the door rack of the freezer. These will help stabilize temperatures when the door is open and in the event of a power outage. Do not over-fill with water bottles and ice packs, impeding airflow.
- Make sure doors close tightly and seals are intact.

- Allow the unit to stabilize overnight and check temperatures in the morning.
- Adjust the dial or thermostat until the target temperature is achieved and held for at least 3 days. Log temperatures at least twice a day during the adjustment period.
- Once the temperature is in range and stabilized, your storage unit is ready to receive vaccine.

## **Vaccine Placement**

- Place vaccine in the middle of the compartment away from ceilings, walls, vents, fans, and coils. In the refrigerator compartment of combined units, keep vaccine away from the vent or fan channeling air from the freezer.
- Never store vaccine in door racks or vegetable bins. Consider removing vegetable bins to facilitate air circulation. This will provide more space for water containers.
- Clearly label vaccine “VFC” and keep it physically separated from private stock.
- Keep vaccine in its original packaging and organize by vaccine type. Consider physically separating vaccines with similar names, packaging, or antigens to avoid administration errors.
- Organize packages so that short-dated vaccine is used first.
- If containers are used to organize vaccine, use only open containers with walls that allow air to circulate, such as wire baskets.
- Never store food or beverages in vaccine storage units. Other biologicals can be stored in vaccine storage units as long as they are physically separated from vaccine to prevent contamination and administration errors.
- Diluent packaged with the vaccine should be stored at the same temperature as the vaccine. Diluent packaged separately from the vaccine can be stored refrigerated or at room temperatures.

## **Temperature Monitoring**

- Monitor temperatures twice a day on vaccine storage units. This is required even when your unit has a continuous monitoring chart/logger, or a temperature alarm (see Section 14 for thermometer requirements).
- Log the twice-daily temperature readings on a form that clearly indicates the date and time of the reading, the initials of the person taking the reading, acceptable temperature ranges, and what to do when temperatures are out of range. The Montana Immunization Program provides temperature logs at [www.immunization.mt.gov](http://www.immunization.mt.gov). Temperature logs must be kept for 3 years and made available during VFC site visits.
- Do not make temperature adjustments without informing the vaccine manager or alternate vaccine manager. Consider posting a sign discouraging temperature adjustments by unauthorized personnel.
- DO NOT adjust temperatures in the evening or before a weekend when temperatures cannot be monitored.
- When adjusting temperatures, make slight changes to the thermostat or temperature dial and allow the unit to stabilize for 30 minutes. (Check your owner’s manual to make sure controller adjustments are in the proper direction.) Check and record the temperature.

- Repeat, until the temperature is comfortably within range and stable.
- Record all temperature adjustments and issues with your storage unit on a Vaccine Storage Trouble-Shooting Record. Logging these events will communicate vaccine storage issues to all staff, and document recurring problems and trends with your unit. This will help catch minor problems early before they lead to major incidents that waste vaccine.
- Be proactive in addressing storage unit issues before they result in vaccine wastage.

### ***Out-of-Range Temperatures***

- If vaccine is exposed to out-of-range storage temperatures, follow the instructions on the Vaccine Incident Report. This document can be found at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link.

## 14. THERMOMETERS (DATA LOGGERS)

### *VFC Thermometer Requirements*

The CDC and the Montana Immunization Program require VFC providers to have a certified calibrated, continuously monitoring thermometer in each VFC vaccine storage unit. The Montana Immunization Program supplies thermometers to all VFC providers in the state (budget permitting).

Definitions:

- **Certified Calibrated** – A thermometer that has a certificate stating it has been tested and calibrated as accurate against NIST or ASTM measurement standards within the timeframe recommended by the manufacturer.
- **Continuously Monitoring** - A thermometer that measures and permanently records temperatures on a predetermined schedule so that the data can be reviewed and permanently archived for three years.

### *State-Supplied Thermometers – Data Loggers*

The Montana Immunization Program provides certified calibrated, continuously monitoring Data Loggers to all VFC providers in Montana. Data Loggers are electronic thermometers that continuously record and store temperature readings and indicate through a warning light when out-of-range temperatures have been encountered. Data Loggers interface with a computer so that data can be removed and saved.

### **Immunization Program Responsibilities**

- The Immunization Program supplies Data Loggers free-of-charge to VFC providers in the state (dependent upon budget and supply). Each Data Logger comes with:
  - Certificate of calibration
  - Extra battery
  - Software for controlling the unit and saving data.
- If a provider chooses to supply their own certified calibrated, continuously monitoring thermometer (as defined above), the Montana Immunization Program must approve the thermometer and issue a memo exempting the provider from using a State-supplied Data Logger.
- The Montana Immunization Program and the Data Logger supplier will provide training, technical support, and written instructions for using the Data Loggers.
- The Montana Immunization Program will facilitate an annual recalibration program for State-supplied Data Loggers at the provider's expense.

### **Provider Responsibilities**

- All VFC providers are required to use a the State-supplied Data Loggers in each VFC vaccine storage unit unless they have a thermometer that meets the VFC requirements as defined above or they have a memo from the Montana Immunization Program exempting them from the requirement due to supply issues.

- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software.
- Providers are responsible for replacing broken or malfunctioning Data Loggers with an equivalent unit.
- After the first year, providers are responsible for Data Logger yearly calibration. Re-calibration costs approximately 50\$/unit and includes a replacement battery and a loaner for use while the unit is being re-calibrated (terms of recalibration subject to change).
- Providers must have an emergency backup thermometer on hand in the event that the Data Logger breaks or malfunctions. Backup thermometers must be working and reliable but are not required to be certified calibrated or continuously monitoring.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the State.
- **In the routine use of Data Loggers, providers must:**
  - Use the provided software to setup and activate each Data Logger prior to first use.
  - After activation, properly place a Data Logger in each VFC vaccine storage unit.
  - Check and log the temperature readout and the color of the out-of-range light twice daily. Temperature logs are provided at [www.immunization.mt.gov](http://www.immunization.mt.gov).
  - Immediately obtain a Vaccine Incident Report and follow the instructions if out-of-range temperatures are encountered or the out-of-range light is red. Download and save Data Logger data according to the *Data Logger Instruction Guide*.
  - At the end of every month (prior to ordering and reporting vaccine), download, review, and save Data Logger data for the previous month. Save monthly data and temperature logs for three years.
  - Make Data Logger data available for review during VFC site visits from the Montana Immunization Program.

See the *Montana VFC Data Logger Instruction Manual* for specific details.

## 15. MONTHLY VACCINE REPORTS

**Every month that you have publicly supplied vaccine in your inventory, you must submit a Monthly Vaccine Report.** Reports are due on the **5<sup>th</sup> of the month** and account for vaccine from the previous month. You must submit a monthly report even if you did not order or administer publicly purchased vaccine the previous month and even if you are inactivated from ordering VFC vaccine.

Monthly Vaccine Reports are entered into our vaccine ordering system, and therefore, must be in a standardized format and contain specific information. Two formats are acceptable:

- The Monthly Vaccine Report form obtained from our website ([www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link). There is a separate version for public and private providers.
- WIZRD Vaccine Inventory Report – Please contact the Montana Immunization Program for instructions on using this function (444-5580 [hhsiz@mt.gov](mailto:hhsiz@mt.gov)).

### ***Guidelines for Submitting Monthly Vaccine Reports:***

- If using the Monthly Vaccine Report, follow the step-by-step instructions on the first page.
- Record vaccine transfers to and from other VFC providers in Columns D and C, respectively.
- You will be asked to amend your report and your vaccine order will be held if:
  - Column I (doses on hand end of month) does not equal Column B (doses on hand beginning of month) on the next month's report.
  - Your calculated inventory (Column H) is not the same as your actual inventory (Column I).
  - Orders received during the month are not accounted for in Column C (doses received during the month).
  - A significant number of doses are missing.
- Do not record borrowing between public and private stock on your Monthly Vaccine Report (See Borrowing in Section 17 – Managing Inventory).





## 16. ORDERING AND RECEIVING VACCINE

### Overview

VFC vaccine orders are handled by Home IV Pharmacy in Butte, Montana and generally follow the process outline in Figure 3. Please note that varicella-containing vaccines, which must be frozen, ship directly from Merck rather than from McKesson, the VFC vaccine distributor.

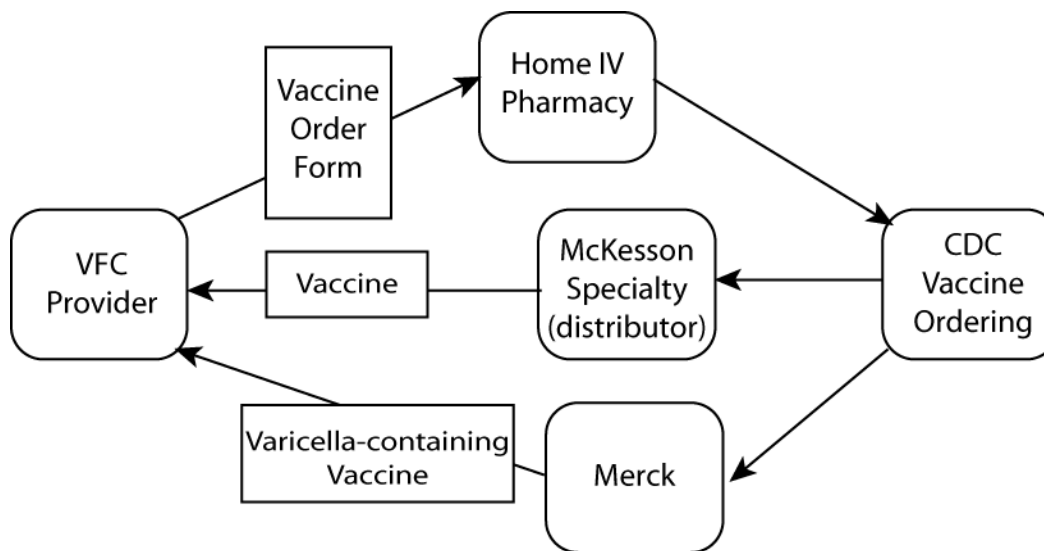


Figure 3 VFC Vaccine Ordering Process

- To order VFC vaccine, submit a Vaccine Order Form to Home IV Pharmacy by mail or by fax. Order forms are available on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link. The Home IV Pharmacy address and fax number are on the form. **If you fax the order form, please also send a copy by mail.** Your order will be delayed if faxes are not received or are unreadable.
- All orders must be accompanied by a complete inventory of your entire VFC vaccine stock (not just vaccines you are ordering). If you submit your order with your monthly report, your monthly report serves as the inventory. If you submit an order without the monthly report then you must fill in the “Doses on Hand” column on the order form.

### Order Frequency and Quantity

- Order VFC vaccine **no more than once per month** and less frequently if you are a low-volume provider. We encourage providers to order as infrequently as possible.
- More than one order per month may be allowed in emergencies but must be accompanied by a full inventory of your VFC vaccine (recorded in the “Doses on hand” column on the order form).
- When ordering, try to maintain a 3–4 month supply of vaccine in inventory, including the order you are placing.

- VFC vaccine must be ordered by dose and by the minimum order quantities listed on the order form. Boxes cannot be broken up into smaller quantities.
- If you routinely use combination vaccines, please limit orders of duplicate single-antigen vaccines (e.g., limit orders of IPV if you routinely administer Pediarix® or Pentacel®).
- Our contract pharmacist reviews orders to ensure they are:
  - Submitted with an accurate monthly report or otherwise accompanied by a full VFC vaccine inventory
  - Not over a 3–4 month's supply for your facility based on usage history
  - Not over-ordering a single-antigen presentation when combination vaccines are in inventory.
- The pharmacist may adjust orders that do not conform to the requirements listed above. Issues with monthly reports, order quantities, and faxed documents may delay orders.
- Please inform Home IV Pharmacy if there is a special circumstance such as a campaign or catch-up clinic where you need more vaccine than your usage history allows.

## ***Receiving Orders***

- If your vaccine shipping address or times vaccine can be received at your facility changes, please inform the Montana Immunization Program (444-5580 [ahs@mt.gov](mailto:ahs@mt.gov)).
- You should receive VFC vaccine 10–14 days after submitting your order to Home IV Pharmacy. Varicella-containing vaccine ships directly from the manufacturer and may take longer to arrive.
- If you have not received your order in two weeks, call Home IV Pharmacy (723-4099) to check on its status.
- Follow the procedures below when receiving vaccine at your facility:
  - Inform front desk and supply personnel when vaccine deliveries are expected. **DO NOT leave vaccine deliveries unattended.** Check all deliveries to determine if they are perishable vaccine.
  - Contact the designated vaccine manager or alternate manager when shipments arrive (See Section 12 for contact information).
- Follow the instructions on the packing slip when unpacking vaccine shipments. Be sure to check that:
  - The package is not damaged or leaking
  - The temperature monitors are within acceptable temperature range
  - The vaccine quantities, lot numbers, and expiration dates match the packing list
  - Expiration dates are compared to current stock to ensure short-dated vaccine is used first.

## ***Problems with Orders***

Never reject VFC vaccine delivery or discard VFC vaccine shipments.

Contact Home IV Pharmacy if you encounter problems with vaccine orders or shipments: 723-4099  
[jerrydotter@bresnan.com](mailto:jerrydotter@bresnan.com) fax 723-4059.

Please note that VFC vaccine orders may have been adjusted to conform to the ordering requirements specified in this section. Contact Home IV Pharmacy if you have questions.



## 17. MANAGING INVENTORY

Please follow the guidelines below in managing your vaccine inventory.

### ***Organizing and Rotating Stock***

- Physically separate VFC vaccine from private stock vaccine and label the boxes accordingly.
- Organize vaccine so that short-dated vaccines (those that expire at the earliest date) are used first. Please note that recently received vaccine may outdate sooner than vaccine already in your inventory. Check expiration dates carefully.
- Also see Section 13, Vaccine Placement (page 51) for additional guidance on organizing your vaccine inventory.

### ***Short-Dated Vaccine***

- Monitor VFC vaccine expiration dates when you list them on your Monthly Vaccine Report.
- If vaccine is within 3 months of expiring and you will not use it in that timeframe, contact other VFC providers in your area to see if they can use it.
- If you cannot find a VFC provider in your area that can use the vaccine, contact the Immunization Program to have it placed on our Short-Dated Vaccine List. The Short-Dated Vaccine List can be found on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov) under the VFC link.
- If another provider can use the vaccine, follow the guidelines below (Vaccine Transfers) when transferring the vaccine.
- Do not transfer short-dated vaccine to providers without first contacting them to see if they can use it before it expires.
- If vaccine on our Short-Dated Vaccine List is transferred to another provider, please notify the Montana Immunization Program (444-5580 [hhsiz@mt.gov](mailto:hhsiz@mt.gov)) so we can remove it from the list.

### ***Vaccine Transfers***

- Transfer VFC vaccine between currently enrolled VFC providers only.
- Follow the *Vaccine Management Plan* (Section 12, page 45) when packing vaccine for transfer.
- Limit transfers to those that can be personally carried and where the vaccine can reach an approved storage unit within 4 hours. Commercial carriers may be used in emergencies. Contact the Immunization Program if you have an emergency.
- Do not transfer opened multi-dose vials.
- Account for transferred vaccine on your Monthly Vaccine Report to Home IV Pharmacy.

## ***Expired and Wasted Vaccine***

Expired vaccine is vaccine that was not used by its expiration date. Wasted vaccine is vaccine that is spoiled due to cold chain failure, mishandling, or packaging malfunction. Follow the guidelines below in handling expired and wasted vaccine.

- DO NOT DISCARD expired and wasted vaccine. Wasted and expired vaccine must be returned to McKesson, our vaccine distributor.
- Obtain an Expired and Wasted Vaccine Return Form from our website ([www.immunization.mt.gov](http://www.immunization.mt.gov)) and follow the instructions on the form.
- Fax a copy of the form to the Immunization Program, keep a copy for your records, and include the original in the box with the returned vaccine.
- Contact the Immunization Program to request a shipping label.

## ***Borrowing***

Vaccine “borrowing” is the temporary transfer of vaccine between public and private stock at a VFC provider facility. VFC providers are required to maintain adequate inventory of public and private vaccine to meet the needs of their patients. Borrowing should not be a routine vaccine management practice. Limited borrowing is allowed in the VFC Program in response to unforeseen circumstances such as delayed or spoiled vaccine shipments, order miscalculations, and billing errors. All borrowing should be paid back at the first opportunity.

Use the following procedures to track vaccine borrowing:

- Document borrowing on the VFC Vaccine Borrowing Report, available on our website at [www.immunization.mt.gov](http://www.immunization.mt.gov). The instructions are on the report.
- Keep the report for your records and make it available for review during VFC site visits. Do not submit borrowing reports to the Immunization Program.
- Do not track borrowing on your Monthly Vaccine Report as doses received or lost (Columns C and D).
- Any dose administered to a VFC-eligible child, whether borrowed (and eventually paid back) from private stock or from VFC stock should be entered on the Monthly Vaccine Report as a dose administered in the appropriate age cohort.
- Do not enter doses borrowed *from* VFC stock (for private stock patients) on the Monthly Vaccine Report.